

REMARKS

Claims 30-45 are currently pending. Claims 30-32 and 35-45 have been amended. Support for these amended claims can be found throughout the specification, e.g., on page 8, line 27; page 12, line 19 to 22; page 13, line 15 to 19; page 18, line 7 to 11. It is respectfully submitted that no new matter has been added by virtue of this amendment.

CONCLUSION

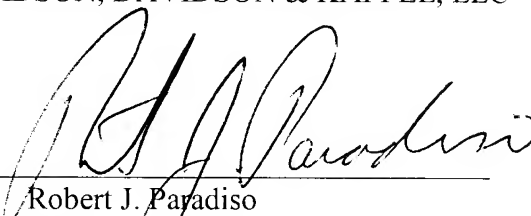
Applicants respectfully request that the amendments made be considered and made of record.

It is believed that no fee is due for the submission of this Preliminary Amendment. If any fees are deemed to be due, the Assistant Commissioner is hereby authorized to charge said fee to Deposit Account No. 50-0552.

An early and favorable decision is earnestly solicited.

Respectfully submitted,

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IN THE SPECIFICATION

Please amend the specification as follows:

At page 1, please amend the title of the invention as follows:

--ANALGESIC COMBINATION OF OXYCODONE AND [SC-58215] 5-(4-FLUOROPHENYL)-1-[4-METHYLSUFONYL]- PHENYL]-3-TRIFLUOROMETHYL 1H-PYRAZOLE.--

At page 13, please amend the paragraph beginning at line 25 as follows:

- - Certain preferred COX-2 inhibitors include celecoxib (SC-58635), [DUP-697] 5-bromo-s-(4-fluorophenyl)-3-[4-(methysulfonyl)phenyl] thiophene (DUP-697), flosulide (CGP-28238), meloxicam, 6-methoxy-2 naphthylacetic acid (6-MNA), Vioxx (MK-966), nabumetone (prodrug for 6-MNA), nimesulide, [NS-398] N-[2-(cyclohexyloxy)-4-nitrophenyl] methanesulfonamide (NS-398), [SC-5766] 1-fluoro-4-[2-[4-methylsulfonyl]phenyl]-1-cyclopenten-1-yl] benzene (SC-5766), [SC-58215] 5-(4-fluorophenyl)-1[4-(methysulfonyl)phenyl]-3-trifluoromethyl 1H-pyrazole (SC-58215), [T-614] N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide (T-614); or combinations thereof. --

IN THE CLAIMS

30.(Amended) A pharmaceutical composition comprising an analgesic combination consisting essentially of [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof; and oxycodone and/or at least one pharmaceutically acceptable salt thereof.

31. (Amended) The pharmaceutical composition according to claim 30, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof would be sub-therapeutic if administered without the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof.

32. (Amended) The pharmaceutical composition according to claim 30, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof; and [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof are administered orally, via implant, parenterally, sublingually, rectally, topically, or via inhalation.

35. (Amended) The pharmaceutical composition according to claim 30, wherein the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof synergistically potentiates the effect of the oxycodone and/or at least one pharmaceutically acceptable salt thereof but the oxycodone and/or at least one pharmaceutically acceptable salt thereof does not synergistically potentiate the effect of the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof.

36. (Amended) The pharmaceutical composition according to claim 34, wherein the oral solid dosage form includes a sustained release carrier which causes the sustained release of the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof; [,] the oxycodone and/or at least one pharmaceutically acceptable salt thereof; [,] or both the oxycodone and/or at least one pharmaceutically acceptable salt thereof and the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof when the dosage form contacts gastrointestinal fluid.

37. (Amended) A method of effectively treating pain in humans or other mammals, comprising administering to a patient an analgesic combination consisting essentially of [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof; and oxycodone and/or at least one pharmaceutically acceptable salt thereof such that the dosing interval of the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof overlaps with the dosing interval of the oxycodone and/or at least one pharmaceutically acceptable salt thereof.

38. (Amended) The method of claim 37, wherein the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof; and the oxycodone and/or at least one pharmaceutically acceptable salt thereof are administered orally.

39. (Amended) The method of claim 37, wherein the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof and the oxycodone and/or at least one pharmaceutically acceptable salt thereof are administered in a single oral dosage form.

40. (Amended) The method of claim 37, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof would be sub-therapeutic if administered without the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof.

41. (Amended) The method of claim 37, wherein the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof is administered before, simultaneously with, or after administration of the oxycodone and/or at least one pharmaceutically acceptable salt thereof, such that the dosing interval of the [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof overlaps with the dosing interval of the oxycodone and/or at least one pharmaceutically acceptable salt thereof.

42. (Amended) A method of reducing the oxycodone and/or at least one pharmaceutically acceptable salt thereof required to treat a patient affected with pain, comprising co-administering said oxycodone and/or at least one pharmaceutically acceptable salt thereof with [said SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof, to augment the analgesia attributable to said oxycodone and/or at least one pharmaceutically acceptable salt thereof during at least a portion of the dosage interval of said oxycodone and/or at least one pharmaceutically acceptable salts thereof.

43. (Amended) A method of reducing the amount of [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof required to treat a patient affected with pain comprising co-administering said [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof with an effective amount of oxycodone and/or at least one pharmaceutically acceptable salt thereof, to augment the analgesia attributable to said [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof during at least a portion of the dosage interval of said [SC-58215] 5-(4-fluorophenyl)-1-[4-methylsulfonyl]phenyl]-3-trifluoromethyl 1H-pyrazole and/or at least one pharmaceutically acceptable salt thereof.

44. (Amended) The pharmaceutical composition according to claim [1] 30, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof is present in an amount from about 2.5 mg to about 800 mg.

45. (Amended) The method of claim 37, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof is present in an amount from about 2.5 mg to about 800 mg.